K090205

APR 2 8 2009

510(k) Summary of Safety and Effectiveness

Manufacturer:	Smiths Medical
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Contact Person:	Donald Alexander Director Regulatory Affairs
Date Prepared:	January 23, 2009
Proprietary Name:	BCI® WW1021 PC Application Software
Common/Classification Name:	Oximetry PC Software
Product Code:	DQA
Regulation Number:	870.2700 (Class II)
Predicate Devices:	BCI® WW1621 Oximetry Data Management Oximetry Software

Device Description:

The aim of this submission is to obtain market clearance for the BCI® WW1021 PC Application Oximetry Software.

The BCI® WW1021 is intended for use with any device which supports the BCI® Communication Protocol (BCICP), if the device is connected to the PC through the USB port. It can be used to configure the device; view the data being recorded in real time; download the recorded data to the PC from the device; analyze and print the recorded data; view event logs and self diagnostic information from the device and can be used in sleep screening. It can show only visual alarms and cannot annunciate audio alarms. It is not intended to be used as a central station monitoring system or as a patient monitoring system. It cannot be used to configure or download data to the PC from devices that are wirelessly connected. It may be used by physicians, respiratory therapists, nurses, certified nurse assistants, emergency medical technicians, sleep technicians and other qualified health care providers. BCI® WW1021 may be used in the hospital or clinical environment. Communication between the device and BCI® WW1021 is possible using any standard USB cable.

Indications for Use

The WW1021 is intended for use with any oximeter/device which supports the BCI® Communication Protocol 1030 (BCICP 1030), if the device is connected to the PC through the USB port. It can be used to view the data being recorded in real time; download the recorded data to the PC from the device; analyze and print the recorded data and can be used in sleep screening. It can show only visual alarms and cannot annunciate audio alarms. It is not intended to be used as a central station monitoring

system or as a patient monitoring system. It may be used by physicians, respiratory therapists, nurses, certified nurse assistants, sleep technicians and other qualified health care providers. The WW1021 may be used in the hospital or clinical environment.

Risk Mitigation Table

Below is a summary of risks common to pulse oximeters and how this submission addresses those risks.

Identified Risk	**Mitigation Measures**
Inadequate Device Performance	Software Validation (Volume 8) Clinical Testing (Volume 10)
Improper Use	Proposed Labeling (Volume 7)

An in-depth risk management analysis, including mitigation measures, was performed on the BCI WW1021 software. The results are provided under Volume 5.

Performance Testing

The BCI WW1021 PC Application Software passed software verification and validation testing. Test reports, including test protocols, pass/fail criteria, results and conclusions, are provided under Volume 8.

Clinical Testing

The intent of this study was to re-analyzed clinical data previously gathered for the investigation of the BCI® 1621 Software to determine the clinical accuracy and functionality of the BCI® WW1021 software's desaturation detection algorithm. There were four subjects enrolled. One subject (Subject A) was studied twice. Subjects included those not suspected of having obstructive sleep apnea, those with the diagnosis of sleep apnea or those suspected of having sleep apnea determined by self disclosure. This study was a descriptive, cross-sectional investigation of adult subjects including those not suspected of having obstructive sleep apnea, those with the diagnosis of sleep apnea or those suspected of having sleep apnea determined by self disclosure. This study involved the comparison to clinician scoring of desaturation events using the definition used by the BCI® WW1021 Software. The Clinical Investigation results were 7.49% false negative and 0.17% false positive events. This constitutes a pass condition for both the false negative (less than or equal to 10%) and false positive (less than or equal to 10%) criteria. A complete test protocol and results can be found under Volume 10.

Conclusion

Supporting information per this premarket submission confirms that the BCI® WW1030 Pulse Oximeter is substantially equivalent to its predicate devices.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2009

Mr. Donald Alexander
Director Regulatory Affairs
Smiths Medical PM, Incorporated
N7 W22025 Johnson Drive
Waukesha, Wisconsin 53186-1856

Re: K090205
Trade/Device Name: BCI WW1021
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: January 23, 2009
Received: January 28, 2009

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: BCI® WW1021 PC Application Software

Indications for Use:

WW1021 is intended for use with any oximeter/device which supports the BCI® Communication Protocol 1030 (BCICP 1030), if the device is connected to the PC through the USB port. It can be used to view the data being recorded in real time; download the recorded data to the PC from the device; analyze and print the recorded data and can be used in sleep screening. It can show only visual alarms and cannot annunciate audio alarms. It is not intended to be used as a central station monitoring system or as a patient monitoring system. It may be used by physicians, respiratory therapists, nurses, certified nurse assistants, sleep technicians and other qualified health care providers. WW1021 may be used in the hospital or clinical environment.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090265